

1670. Adulteration and misbranding of gauze pads. U. S. v. 46 Packages of Gauze Pads. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 16338. Sample No. 4610-H.)

LIBEL FILED: June 2, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 11, 1944, from Worcester, Mass., by the Handy Pad Supply Co.

PRODUCT: 46 packages of gauze pads at Philadelphia, Pa.

LABEL, IN PART: (Package) "100 Ideal Dispenser Type Gauze Pads Sterilized After Packaging."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Sterile Absorbent Gauze [Sterile Gauze]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statement, "Sterilized After Packaging," was false and misleading as applied to the article, which was not sterile but was contaminated with living micro-organisms.

DISPOSITION: August 29, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable institution.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1671. Misbranding of estrogenic hormone. U. S. v. 87 Vials of Estrogenic Hormone. Default decree of condemnation. Product ordered delivered to a charitable organization. (F. D. C. No. 16241. Sample No. 22578-H.)

LIBEL FILED: May 25, 1945, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about April 27 and 28, 1945, from Philadelphia, Pa., by the National Drug Co.

PRODUCT: 87 vials of *estrogenic hormone* at St. Louis, Mo. Examination showed that the article was an oil solution containing estrogenic substances consisting essentially of estradiol with an insignificant amount, if any, of estrone which is the principal estrogenic hormone occurring in natural sources such as pregnant mares' urine.

LABEL, IN PART: "10 cc. Estrogenic Hormone 10,000 Injectosol * * * An estrus producing extract derived from pregnant mares' urine."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "derived from pregnant mares' urine," was false and misleading since the estrogenic material present in the article did not consist of estrogenic substance as derived from the urine of pregnant mares.

DISPOSITION: July 10, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable organization on condition that the product be relabeled, under the supervision of the Federal Security Agency, to show that it was essentially estradiol.

1672. Misbranding of estrogenic substance in oil. U. S. v. 2,167 Vials of Estrogenic Substance in Oil. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 16000. Sample Nos. 13251-H, 13252-H.)

LIBEL FILED: May 4, 1945, Southern District of Ohio.

ALLEGED SHIPMENT: On or about January 30 and March 5, 1945, by the Loeser Laboratory, Inc., from New York, N. Y.

PRODUCT: 2,167 20-cc. vials of *estrogenic substance in oil* at Cincinnati, Ohio. Examination showed that the product was an oil solution containing estrogenic substances consisting almost entirely of estradiol with an insignificant amount, if any, of estrone, which is the principal estrogenic hormone occurring in natural sources such as pregnant mares' urine.

LABEL, IN PART: "Proliculin Natural Estrogenic Substances in Oil [or "Proliculin Brand of Natural Estrogenic Substance in Oil"] * * * Derived from the urine of pregnant mares."

*See also Nos. 1651, 1652, 1654, 1655, 1658, 1664, 1669, 1670.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements, "Natural Estrogenic Substance [or "Substances"] in Oil" and "Natural Estrogenic Substance [or "Substances"] * * * Derived from the urine of pregnant mares," were false and misleading since the estrogenic material present did not consist of natural estrogenic substance as derived from the urine of pregnant mares.

DISPOSITION: June 18, 1945. The Wm. S. Merrell Co., Cincinnati, Ohio, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1673. Misbranding of thyroid tablets. U. S. v. 1,331 Bottles, 46 Bottles, and 205 Bottles of Thyroid Tablets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15789. Sample Nos. 29397-H to 29400-H, incl., 29417-H to 29420-H, incl.)

LIBEL FILED: April 9, 1945, Northern District of California.

ALLEGED SHIPMENT: Between the approximate dates of January 21, 1944, and February 8, 1945, from Detroit, Mich., by Parke, Davis and Co.

PRODUCT: 1,331 100-tablet bottles, 46 500-tablet bottles, and 205 1,000-tablet bottles of *thyroid tablets* at San Francisco, Calif. Examination of samples showed that the product contained thyroid equivalent to approximately 1½ times the grainage stated on the respective labels as calculated from the iodine content to the standard prescribed by the United States Pharmacopoeia.

LABEL, IN PART: "C. T. [or "C. C. T."] Thyroid Glands," and "Emplets Thyroid Gland."

NATURE OF CHARGE: Misbranding, Section 502(a), the statements on the labels of various portions of the article, "¼ Grain," "½ Grain," "1 Grain," "2 Grains," and "5 Grains," were misleading because the quoted declarations created the impression that the article contained, respectively, the declared amounts of thyroid of the standard potency as specified in the United States Pharmacopoeia, whereas the article contained approximately 1½ times the declared number of grains of thyroid of such standard potency; and such impression was not corrected by the label statements, "Thyroid Gland 50% Stronger than U. S. P.," or "Contains Desiccated Thyroid Gland 50% Stronger than U. S. P.," and "Contains 0.3% iodine," and (upon some of the labels) "Equivalent to ⅜ gr. Thyroid U. S. P.," and "Equivalent to 7½ grains Thyroid U. S. P."

Further misbranding, Section 502 (a), the label statement, "The high iodine content is obtained by careful selection of fresh glands," was false and misleading since the glands used were not selected but were the ordinary quality of glands as supplied generally by packing houses.

DISPOSITION: August 13, 1945. Parke, Davis and Co., Detroit, Mich., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for reprocessing or other lawful disposition under the supervision of the Federal Security Agency.

1674. Misbranding of granulated cramp bark. U. S. v. 7 Barrels of Granulated Cramp Bark. Consent decree of forfeiture. Product ordered released under bond. (F. D. C. No. 16261. Sample No. 24449-H.)

LIBEL FILED: June 4, 1945, Northern District of Texas.

ALLEGED SHIPMENT: On or about April 20, 1945, by J. L. Hopkins and Co., from New York, N. Y.

PRODUCT: 7 barrels of *granulated cramp bark* at Dallas, Tex. Examination showed that this product was maple bark and not cramp bark.

LABEL, IN PART: "Granulated Cramp Bark, so Called for Manufacturers Use."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation, "Cramp Bark, so Called" was false and misleading as applied to maple bark; and, Section 502 (e) (1), the label failed to bear the common or usual name of the article.

DISPOSITION: June 22, 1945. The First Texas Chemical Manufacturing Co., Dallas, Tex., having admitted the facts set forth in the libel, judgment of forfeiture was entered and the product was ordered released under bond to be relabeled and brought into compliance with the law, under the supervision of the Food and Drug Administration.